

**REMARKS/ARGUMENTS**

By this Amendment, claims 30-31, 36-37, and 46-65 are canceled; claims 1, 3 and 29 are amended. Claims 1-3, 29, 32-35, and 38-45 are pending.

Cancellation of and/or amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The cancellation and/or amendments to the claims are being made solely to expedite prosecution of the instant application.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Reconsideration of the restriction requirement is respectfully requested.

Applicants hereby affirm their prior election with traverse of Group I, claims 1-3, and 29-45, reserving their rights under 35 USC § 121 to file a divisional application for the nonelected claims.

**Rejection under 35 USC § 112 second paragraph**

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the recitation in claim 3 of the term "2" is confusing. This rejection is respectfully traversed. However, solely to expedite prosecution, Applicant has amended claim 3 to remove the reference to claim 2. The claim is definite, and reconsideration and withdrawal of the rejection is respectfully requested.

**Rejection under 35 USC § 102(a)/102(e)**

Claims 1-3, and 29 stand rejected under 35 U.S.C. 102(a,e) as allegedly being anticipated by Sambasivam et al. U.S. Patent No. 6,603,022. 102(a) rejection is in light of publication date, which is 08/05/2003 of US 6,603,022, and 102(e) is in light of filing date, which is 07/12/2002 of U.S. Patent No. 6,603,022 vs. the effective filing date of the instant application, which is 01/02/2004. This rejection is respectfully traversed.

The Examiner alleges that the '022 patent discloses the instantly claimed process in columns 15-18, wherein R1 and R2 are listed as being heteroalkyl, heteroaryl, moiety or R1 and R2 being together heterocyclic moiety. However, the claims are novel over the disclosure of the '022 patent for the following reasons. In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the '022 patent. The '022 patent discloses a method of synthesis of simvastatin wherein the statin-type starting material is reacted with a secondary amine, comprising R1 and R2 groups, wherein R1 and R2 are each independently an alkyl, heteroalkyl, aryl or heteroaryl moiety, or R1 and R2, taken together, form a heterocyclic moiety having 5-8 atoms (column 16, lines 55-64, and claim 1). However, the instant claims are directed to a process wherein lovastatin is reacted with a compound having the formula  $\text{HNR}_1\text{R}_2$ , wherein  $\text{R}_2$  is H. This limitation is not disclosed in the '022 patent. Since this limitation is not disclosed in the '022 patent, the patent does not disclose each and every limitation of the claims,

and the patent does not anticipate the instant claims.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-3, and 29 under 35 USC 102(a, e) is respectfully requested.

**Rejection under 35 USC § 103(a)**

Claims 1-3, and 29-45 stand rejected under 103(a) as allegedly being unpatentable over Sambasivam et al. U.S. Patent No. 6,603,022 and Kumar et al., U.S. Patent No. 5,763,646. This rejection is respectfully traversed.

The Examiner alleges that the '022 patent discloses analogous processes for obtaining Simvastatin using the same R1 and R2 substituents without hydroxyl protecting groups. The Examiner further alleges that the '646 patent in columns 3-4 disclosed analogous processes for obtaining Simvastatin using different R1 and R2 as amid substituents with hydroxyl protecting groups. The examiner argues that the difference between the instant claims and the prior art process is that the process disclosed in the '022 patent does not include hydroxyl-protecting groups. The process disclosed in the '646 patent has different R1 and R2 substituents. The Examiner alleges that one having ordinary skill in the art would be motivated to modify the process of the '022 patent without hydroxyl protecting groups to the process of the '646 patent with the different R1 and R2 substituents.

However, the claims are patentable over the '022 and '646 patents for the following reasons. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), MPEP 2143.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). MPEP 2143.03. Here, the '022 patent discloses a method of synthesis of simvastatin wherein the statin-type starting material is reacted with a secondary amine, comprising R1 and R2 groups, wherein R1 and R2 are each independently an alkyl, heteroalkyl, aryl or heteroaryl moiety, or R1 and R2, taken together, form a heterocyclic moiety having 5-8 atoms (column 16, lines 55-64, and claim 1). However, the '022 patent does not disclose or suggest a method wherein R2 is H. This deficiency is not cured by the '646 patent which discloses a process for preparing simvastatin by reacting lovastatin with one of the compounds of C3-C6-n-alkylamine or C3-C6-cycloalkylamine to produce lovastatin alkyl or cycloalkylamide, C-methylating at alpha position of 2-methyl butyryl side chain, deprotecting, hydrolyzing the amide linkage and lactonizing. The instantly claimed process uses neither C3-C6-n-alkylamine nor C3-C6-cycloalkylamine. The '646 patent is silent with regards to a method of producing simvastatin by reacting lovastatin with a secondary amine, comprising R1 and R2 groups, wherein the R2 is H. Therefore, the

combination of the '022 patent and the '646 patent do not teach or suggest all the limitations of the claims.

Furthermore, there is no motivation for one of skill in the art to alter the methods of the '022 patent or '646 patent to arrive at the claimed method, and no reasonable expectation of success. There is no teaching or suggestion within the '646 patent to alter the method disclosed in the '022 patent to arrive at the instantly claimed method. The Examiner argues that the motivation is to modify the process of the '022 patent without hydroxyl protecting groups to the instant process with the '646 patent process with the different R1 and R2 substituents. However, the combination of the '022 patent and the '646 patent does not disclose or suggest methods wherein R2 is H, or the instantly claimed method in which neither C3-C6-n-alkylamine nor C3-C6-cycloalkylamine are used. Since the combination of the patents does not disclose or suggest these limitations, there is no motivation to combine the references to reach these limitations, and no expectation of success.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-3, and 29-45 under 35 USC 103(a) is respectfully requested.

\*

\*

\*

Application No. 10/539,736  
Amendment Dated 12/14/2006  
Reply to Office Action of June 26, 2006

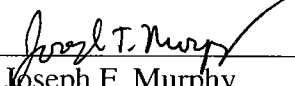
For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

December 14, 2006

By   
Joseph F. Murphy  
Registration No. 58,313  
Customer No. 03000  
(215) 567-2010  
Attorneys for Applicants

Please charge or credit our  
Account No. 03-0075 as necessary  
to effect entry and/or ensure  
consideration of this submission.